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IS 3234-1 (1986): Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment, Part 1: General requirements [MHD 12: Hospital Equipment]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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*Indian Standard***SPECIFICATION FOR
CONICAL FITTINGS WITH A 6 PERCENT (LUER) TAPER FOR
SYRINGES, NEEDLES AND OTHER MEDICAL EQUIPMENT****PART 1 GENERAL REQUIREMENTS***(Second Revision)*

[ISO Title : Conical Fittings with a 6% (Luer) Taper for Syringes,
Needles and Certain Other Medical Equipment—
Part 1 : General Requirements]

National Foreword

This Indian Standard (Part 1), which is identical with ISO 594/1-1986 'Conical fittings with a, 6% (Luer) taper for syringes, needles and certain other medical equipment-Part 1 : General requirements', issued by the International Organization for Standardization (ISO), was adopted by the Indian Standards Institution on the recommendations of the Medical Glass Instruments and Appliances Sectional Committee and approval of the Consumer Products and Medical Instruments Division, Council.

In order to safeguard the national interest, the temperature at which the gauging test and stress cracking test, as mentioned in clauses 5.1 and 6.6, are conducted may be 27%. This temperature has also been accepted by ISO for tropical countries.

In the adopted standard, certain terminology and conventions are not identical with those used in Indian Standards; attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear, referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

Adopted 27 October 1986

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Gr 4

Medical Glass Instruments and Appliances Sectional Committee, CPDC 12 [Ref: Doc: CPDC 12 (1986)]

0 Introduction

In this revision of ISO/R 594 first published in 1967, the opportunity has been taken to incorporate test methods for gauging and performance.

It should be noted that the annex does not form an integral part of the standard.

ISO 594/2 deals with lock fittings.

1 Scope and field of application

This part of ISO 594 specifies requirements for conical fittings with a 6 % (Luer) taper for use with hypodermic syringes and needles and with certain other apparatus for medical use such as transfusion and infusion sets.

It covers conical fittings made of rigid and of semi-rigid materials and includes test methods for gauging and performance. It excludes provision for more flexible or elastomeric materials.

Figure 1 illustrates typical male 6 % (Luer) conical fitting ("male fitting") and female 6 % (Luer) conical fitting ("female fitting").

NOTE – It is not practicable to define the characteristics of rigid or semi-rigid materials with precision, but glass and metal may be considered as typical rigid materials. By contrast, many plastic materials may be regarded as semi-rigid although the wall thickness is an important factor influencing the rigidity of a component.

2 References

ISO 594/2, *Conical fittings with 8.6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings.*¹⁾

ISO 7666, *Sterile hypodermic syringes for single use.*

3 Dimensions

The dimensions of male and female conical fittings shall be as given in the table and as shown in figure 1.

A typical assembly of 6 % (Luer) conical fittings is shown in figure 2.

The dimensions of the assembly shall be as given in the table.

1) At present at the stage of draft

Dimensions in millimetres

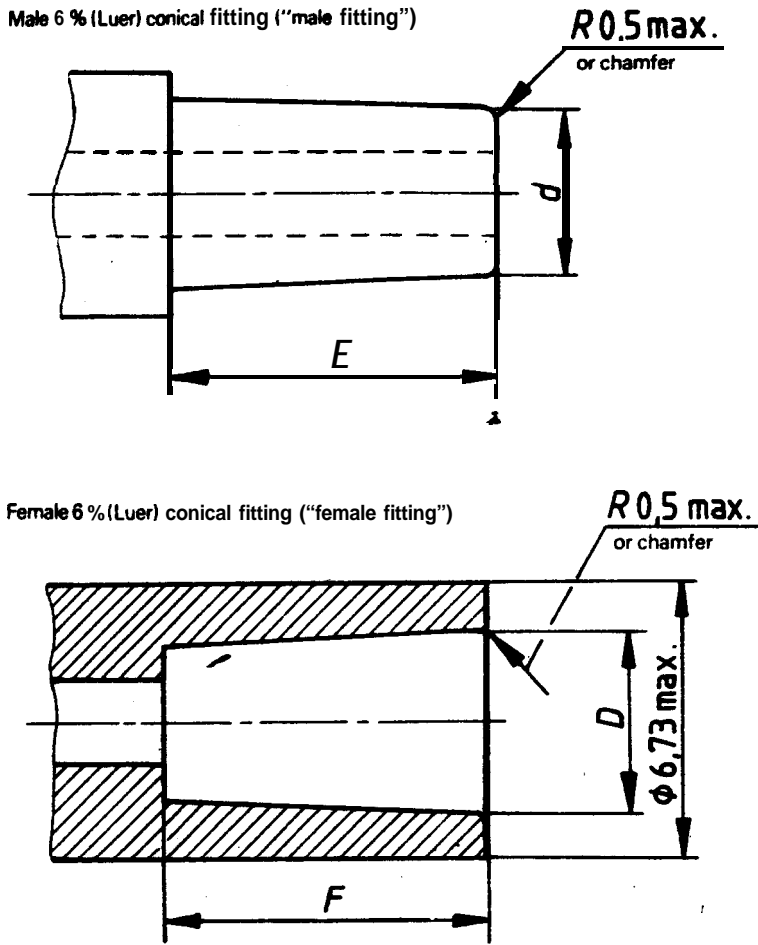


Figure 1 — Typical 6 % (Luer) conical fittings
 (see the corresponding values in the table)

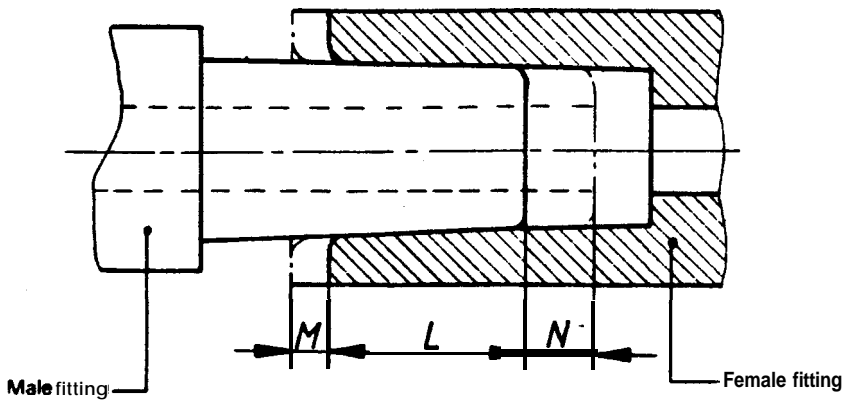


Figure 2 — Typical assembly of 6 % (Luer) conical fittings
 (see the corresponding values in the table)

Table — Dimensions of 6 % (Luer) conical fittings

Reference		Designation	Dimension8 (mm)	
			rigid material	semi-rigid material
Basic dimensions	d { min. max.	Minimum diameter of the end of the male conical fitting (reference diameter)	3,925	3,925
		Maximum diameter at the end of the male conical fitting	3,990	4,927
	D { min. max.	Minimum diameter at the opening of the female conical fitting	4,270	4,270
		Maximum diameter at the opening of the female conical fitting	4,315	4,315
	E	Minimum length of the male conical fitting	7,500	7,500
	F	Minimum depth of the female conical fitting	7,500	7,500
Other dimensions	L*	Minimum length of engagement	4,595	4,959
	M*	Tolerance for length of engagement of the female conical fitting	0,750	0,759
	N*	Tolerance for length of engagement of the male conical fitting	1,083	1,700
	R** max.	Radius of curvature	9,5	0,5

* Dimensions L, M and N are derived from the basic dimensions.

** Or equivalent entry chamfer without any sharp corners

4 Requirements

4.1 Gauging

When tested in accordance with 5.1, the conical fitting shall satisfy the requirements specified in 4.1.1 and 4.1.2.

4.1.1 The small end of the male conical fitting shall lie between the two limit planes of the gauge and the larger end of the tapered portion shall extend beyond the datum plane of the gauge.

Rocking shall not be evident between the gauge and the fitting made of rigid¹⁾ material undergoing test.

4.1.2 The plane of the maximum diameter at the opening of the female conical fitting shall lie between the two limit planes of the gauge.

Rocking shall not be evident between the gauge and the fitting made of rigid¹⁾ material undergoing test.

4.2 Liquid leakage

There shall be no leakage sufficient to form a falling drop of water under the test conditions described in 5.2.

The axis of the conical fitting under test shall be horizontal.

4.3 Air leakage

Continued formation of air bubbles shall not be evident under the test conditions described in 5.3. Bubbles formed during the first 5 s shall be ignored.

4.4 Separation force

The conical fitting under test shall remain attached to the test fixture, under the test conditions described in 5.4.

4.5 Stress cracking

There shall be no evidence of stress cracking of the conical fitting, under the test conditions described in 5.5.

NOTE — Materials used for conical fittings should be resistant to stress cracking in environments likely to be encountered in use (for example when in contact with alcohols).

1) The test for freedom from rocking may be found useful for evaluating semi-rigid fittings

5 Test methods

5.1 Gauging test

The procedure shall be carried out as specified in 5.1.1 to 5.1.4.

5.1.1 Carry out the test using steel gauges as illustrated in figure 3.

5.1.2 Carry out the test at a temperature of $(20 \pm 5)^\circ\text{C}$.

5.1.3 Prior to testing, condition products made from hygroscopic materials at $(20 \pm 5)^\circ\text{C}$ and $(50 \pm 10)\%$ relative humidity for not less than 24 h. Conditioning is not required for products made from non-hygroscopic materials.

5.1.4 Apply the gauge to the conical fitting with a total axial force of 5 N, without the use of torque. Remove the axial load.

5.2 Test method for liquid leakage from the conical fitting assembly under pressure

The procedure shall be carried out as specified in 5.2.1 to 5.2.6.

5.2.1 Connect the conical fitting to be tested to a steel male or female reference fitting, the dimensions of which are in accordance with those shown in figure 4 or 5, as appropriate, both components being dry. Assemble the components by applying an axial force of 27.5 N for 5 s whilst applying a twisting action to a value of torque not exceeding 0,1 N·m to give a rotation not exceeding 90° .

5.2.2 Introduce water into the assembly.

5.2.3 Expel air.

5.2.4 Ensure that the outside of the conical fitting assembly is dry.

5.2.5 Seal the assembly outlet and bring the internal water pressure to an effective pressure of 300 kPa.

5.2.6 Maintain the pressure for 30 s.

NOTE – Other test methods (an example is given in the annex) may be used if good correlation is shown with the reference test specified above.

5.3 Test method for air leakage into the conical fitting assembly during aspiration

5.3.1 Male fittings

The procedure shall be carried out as specified in 5.3.1.1 to 5.3.1.7.

5.3.1.1 Connect the male conical fitting to a female reference fitting the dimensions of which are in accordance with those shown in figure 4, both components being dry. Apply the male fitting to the female reference fitting with an axial force of 27.5 N for 5 s whilst applying a twisting action to a value of torque not exceeding 0,1 N·m to give a rotation not exceeding 90° .

5.3.1.2 Connect the reference female fitting by means of a leakproof joint of minimal volume to a syringe, the latter having previously passed the test for leakage past the piston during aspiration, in accordance with ISO 7886.

5.3.1.3 Draw into the syringe, through the device and the female reference fitting, a volume of recently boiled and cooled water exceeding 25 % of the graduated capacity of the syringe.

5.3.1.4 Expel the air except for a small residual air bubble.

5.3.1.5 Adjust the volume of water in the syringe to 25 % of the graduated capacity.

5.3.1.6 Occlude the device below the conical fitting assembly.

5.3.1.7 With the nozzle of the syringe downwards, withdraw the plunger to nominal capacity. Hold for 15 s.

5.3.2 Female fittings

Conduct the test as for 5.3.1 but using a syringe with a steel male reference fitting in accordance with figure 5 to mate with the female fitting under test.

NOTE – Other test methods (e.g. involving automatic testing) may be used if good correlation is shown with the reference test specified above.

5.4 Test method for separation force of conical fitting assembly

The procedure shall be carried out as specified in 5.4.1 and 5.4.2.

5.4.1 Assemble as for liquid leakage testing in 5.2.

5.4.2 Apply an axial force of 25 N in a direction away from the test fixture at a rate of approximately 10 N/s for a period of not less than 10 s.

5.5 Method of testing for stress cracking

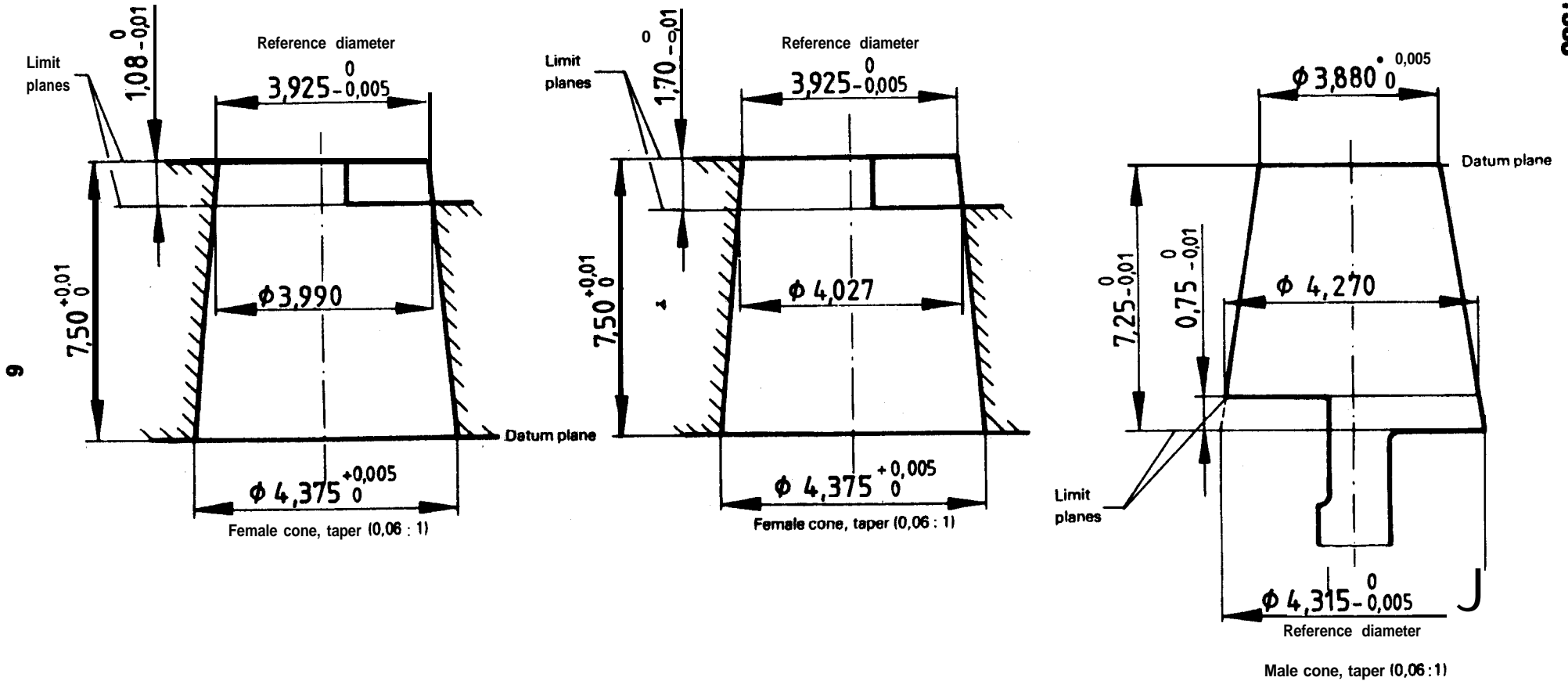
The procedure shall be carried out as specified in 5.5.1 to 5.5.3.

5.5.1 Connect the conical fitting to be tested to a steel male or female reference fitting, the dimensions of which are in accordance with those shown in figure 4 or 5, as appropriate, both components being dry. Assemble the components by applying an axial force of 27.5 N for 5 s whilst applying a twisting action to a value of torque not exceeding 0,1 N·m to give a rotation not exceeding 90° .

5.5.2 For single-use hypodermic needles, leave the fittings assembled for 24 h at $(20 \pm 5)^\circ\text{C}$.

5.5.3 For general equipment other than that described in 5.5.2, leave the fittings assembled for 46 h at $(20 \pm 5)^\circ\text{C}$.

Dimensions in millimetres



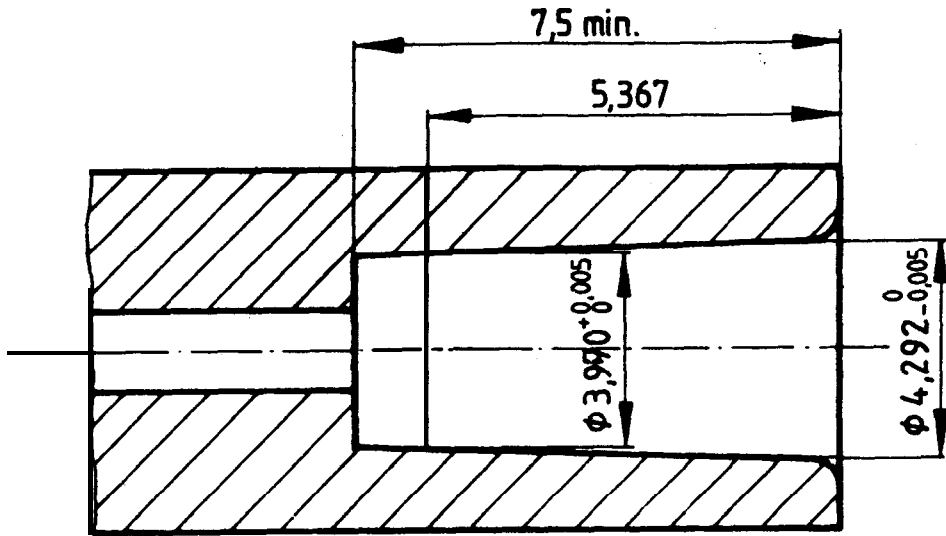
a) Gauge for testing rigid male conical fittings

b) Gauge for testing semi-rigid male conical fittings

c) Gauge for testing female conical fittings of all materials

Figure 3 – Gauges for testing 6% (Luer) conical fittings

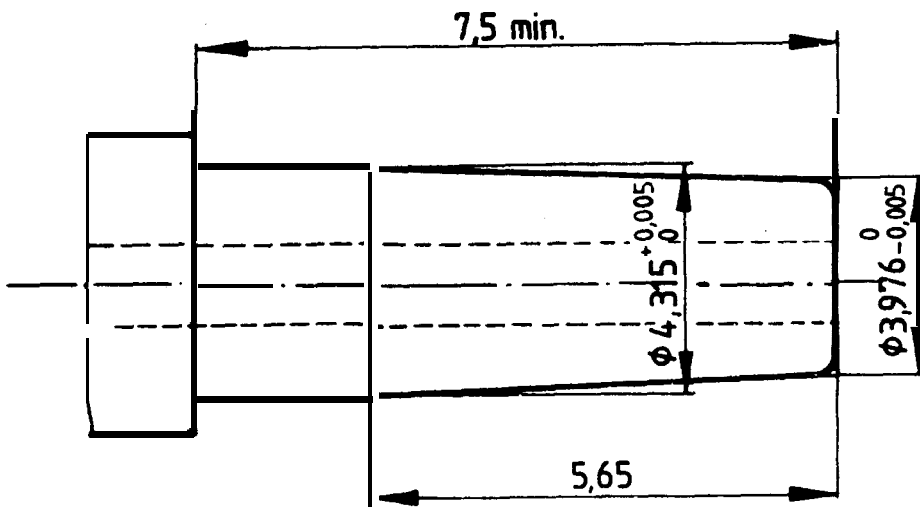
Dimensions in millimetres



Cone taper (0,06 : 1)

Figure 4 – Reference steel **female** conical fitting

Dimensions in millimetres



Cone taper (0,06 : 1)

Figure 5 – Reference **steel** male conical fitting

Annex

Liquid leakage

(This annex, given only as an example, does not form part of the standard.)

A.1 Specification

When testing the leakage characteristics in accordance with clause A.2, the established leakage rate shall not exceed 0,005 Pa·m³/s. This value of the leakage rate shall be considered as a criterion during a test.

A.2 Test method for leakage rate

The procedure shall be carried out as follows:

Connect the conical fitting to be tested to a steel male or female reference fitting the dimensions of which are in accordance with those shown in figure 4 or 5, as appropriate.

Assemble the components by applying an axial force of 27,5 N for 5 s whilst applying a twisting action to a value of torque not exceeding 0,1 N·m to give a rotation not exceeding 90°.

Seal the outlet bore of the fitting under test so that it is airtight.

After connection, apply compressed air at a pressure of approximately 3×10^5 Pa to the fitting in the reference fitting through the bore. Calculate the leakage rate, L , on the basis of the following formula:

$$L = \frac{3 \times 10^5}{p} \times V \times \frac{\Delta p}{\Delta t}$$

where

L is the leakage rate, in pascals cubic metres per second,

V is the volume, in cubic metres, of the test specimen and the experimental apparatus;

Δp is the pressure drop, in pascals, during the test period;

Δt is the test period, in seconds;

p is the test pressure, in pascals.

Example: At a test pressure of $2,9 \times 10^5$ Pa (2,9 bar) and a total volume of 10×10^{-8} m³ (10 ml), a pressure drop of 1×10^4 Pa (0,1 bar) is established within a period of 25 s.

$$L = \frac{3 \times 10^5}{2,9 \times 10^5} \times 10 \times 10^{-8} \times \frac{10^4}{25} = 0,0041 \text{ Pa}\cdot\text{m}^3/\text{s}$$